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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/815,987	03/31/2004	Yi Yan Yang	6565-68316-01/RJP	7283
24197 7590 04/20/2007 KLARQUIST SPARKMAN, LLP 121 SW SALMON STREET SUITE 1600 PORTLAND, OR 97204			EXAMINER AHMED, HASAN SYED	
			ART UNIT	PAPER NUMBER
			1615	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		04/20/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/815,987	Applicant(s) YANG ET AL.	
	Examiner Hasan S. Ahmed	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 April 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) 20-34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/2/04; 8/29/05</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Receipt is acknowledged of applicants': (1) IDS, which was filed on 2 September 2004; (2) supplementary IDS, which was filed on 29 August 2005; and (3) response to restriction requirement, which was filed on 6 April 2007.

* * * * *

Election/Restrictions

Applicant's election without traverse of Group I in the reply filed on 6 April 2007 is acknowledged.

Claims 20-34 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 6 April 2007.

* * * * *

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 12, and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Gutierrez-Rocca (WO 02/067905).

Gutierrez-Rocca discloses:

- the sustained-release formulation of instant claim 1 (see page 2, line 7);
- the tablet of instant claim 1 (see page 2, line 15);

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- the caffeine of instant claim 1 (see page 2, line 22);
- the hydrophilic polymer of instant claim 1 (see page 3, line 19);
- the HPMC of instant claim 2 (see page 3, line 30); and
- the homogeneous mixture of instant claim 3 (see page 7, lines 26-30).

Shaping of the tablet in the form of a donut, as recited in instant claims 12 and 19 is deemed to be a matter of engineering design choice, and thus does not serve to patentably distinguish the claimed subject matter over the prior art. *In re Kuhle*, 526 F. 2d. 553, 188 USPQ 7 (CCPA 1975).

*

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1, 5, and 6 are rejected under 35 U.S.C. 102(a) as being anticipated by Thombre (US 2003/0175326).

Thombre discloses:

- the sustained-release formulation of instant claim 1 (see paragraph 0026);
- the tablet of instant claim 1 (see paragraph 0017);
- the caffeine of instant claim 1 (see paragraph 0059);
- the hydrophilic polymer of instant claim 1 (see paragraph 0088);
- the poly(ethylene oxide) of instant claim 5 (see paragraph 0093 and Table B); and
- the homogenous mixture of instant claim 6 (see paragraph 0068).

* * * * *

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 1 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thombre (US 2003/0175326) in view of Giles, Jr. (US 5,977,120).

Thombre teaches a sustained-release formulation (see above)

The Thombre reference differs from the instant application in that it does not recite kavalactone.

Giles, Jr. teaches a sustained-release composition (see claim 15) comprising:

- the caffeine of instant claim 1 (see col. 2, line 54); and
- the kavalactone of instant claim 11 (see col. 3, line 17).

Giles, Jr. explains that kavalactone is beneficial because of its anti-anxiety effects (see col. 1, lines 44-54).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to disclose a sustained-release tablet comprising caffeine, a hydrophilic polymer, and kavalactone, as taught by Thombre in view of Giles, Jr. One of ordinary skill in the art at the time the invention was made would have been motivated to add kavalactone to such a composition because of its anxiolytic effects, as explained by Giles, Jr.

*

2. Claims 1, 4, 7-10, and 13-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thombre (US 2003/0175326).

Thombre teaches a sustained-release formulation (see above)

While Thombre does not explicitly teach percentages of instant claims 4, 7-9, and 13-17, or the release profiles of instant claims 10 and 18, it would have been obvious to one of ordinary skill in the art at the time the invention was made to determine suitable percentages and release profiles through routine or manipulative experimentation to obtain the best possible results, as these are variable parameters attainable within the art.

Moreover, generally, differences in concentration or release kinetics will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456; 105 USPQ 233, 235 (CCPA 1955). Applicants have not demonstrated any unexpected or unusual results, which accrue from the instant percentages or release profiles.

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Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hasan S. Ahmed whose telephone number is 571-272-4792. The examiner can normally be reached on 9am - 5:30pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


HUMERA N SHEIKH
PRIMARY EXAMINER